

Claims:

1. An abuse-proofed, thermoformed dosage form,
characterised in that, in addition to one or more
5 active ingredients with abuse potential (A) optionally
together with physiologically acceptable auxiliary
substances (B), it contains at least one synthetic or
natural polymer (C) and optionally at least one wax
(D), wherein component (C) exhibits a breaking
10 strength of at least 500 N.
2. A dosage form according to claim 1, characterised in
that it is in the form of a tablet.
- 15 3. A dosage form according to claim 1, characterised in
that it is in multiparticulate form, preferably in the
form of microtablets, micropellets, granules,
spheroids, beads or pellets, optionally pressed into
tablets or packaged in capsules.
- 20 4. A dosage form according to one of claims 1 to 3,
characterised in that the polymer (C) used was at
least one polymer selected from the group consisting
of polyethylene oxide, polymethylene oxide,
25 polypropylene oxide, polyethylene, polypropylene,
polyvinyl chloride, polycarbonate, polystyrene,
polyacrylate, copolymers and the mixtures thereof,
preferably polyethylene oxide.
- 30 5. A dosage form according to one of claims 1 to 4,
characterised in that the polymer (C) has a molecular
weight of at least 0.5 million according to
rheological measurements.

6. A dosage form according to claim 5, characterised in that the molecular weight is 1-15 million.
- 5 7. A dosage form according to one of claims 1 to 6, characterised in that the wax (D) is at least one natural, semi-synthetic or synthetic wax with a softening point of at least 60°C.
- 10 8. A dosage form according to claim 7, characterised in that the wax (D) is carnauba wax or beeswax.
9. A dosage form according to one of claims 1 to 8, characterised in that the component(s) (C) is/are
15 present in quantities such that the dosage form has a breaking strength of at least 500 N.
10. A dosage form according to one of claims 1 to 9, characterised in that the active ingredient (A) is at
20 least one active ingredient selected from the group consisting of opiates, opioids, tranquillisers, stimulants, barbiturates and further narcotics.
11. A dosage form according to one of claims 1-10, characterised in that it additionally comprises at
25 least one of the following components a)-f):
- (a) at least one substance which irritates the nasal passages and/or pharynx,
- 30 (b) at least one viscosity-increasing agent, which, with the assistance of a necessary minimum quantity of an aqueous liquid, forms a gel with

the extract obtained from the dosage form, which gel preferably remains visually distinguishable when introduced into a further quantity of an aqueous liquid,

5

c) at least one antagonist for the active ingredient or active ingredients with abuse potential

(d) at least one emetic,

10

(e) at least one dye as an aversive agent,

(f) at least one bitter substance.

15 12. A dosage form according to claim 11, characterised in that the component (a) irritant substance causes burning, itching, an urge to sneeze, increased formation of secretions or a combination of at least two of these stimuli.

20

13. A dosage form according to one of claims 11 or 12, characterised in that the component (a) irritant substance is based on one or more constituents of at least one hot substance drug.

25

14. A dosage form according to claim 13, characterised in that the hot substance drug is at least one drug selected from the group consisting of *Allii sativi bulbus* (garlic), *Asari rhizoma cum herba* (Asarum root and leaves), *Calami rhizoma* (calamus root), *Capsici fructus* (capsicum), *Capsici fructus acer* (cayenne pepper), *Curcumae longae rhizoma* (turmeric root), *Curcumae xanthorrhizae rhizoma* (Javanese turmeric

30

root), Galangae rhizoma (galangal root), Myristicae semen (nutmeg), Piperis nigri fructus (pepper), Sinapis albae semen (eruca/white mustard seed), Sinapis nigri semen (black mustard seed), Zedoariae rhizoma (zedoary root) and Zingiberis rhizoma (ginger root), particularly preferably at least one drug selected from the group consisting of Capsici fructus (capsicum), Capsici fructus acer (cayenne pepper) and Piperis nigri fructus (pepper).

10

15. A dosage form according to claim 13 or 14, characterised in that the constituent of the hot substance drug is an o-methoxy(methyl)phenol compound, an acid amide compound, a mustard oil or a sulfide compound or is derived from such a compound.

15

16. A dosage form according to one of claims 13 to 15, characterised in that the constituent of the hot substance drug is at least one constituent selected from the group consisting of myristicin, elemicin, isoeugenol, β -asarone, safrole, gingerols, xanthorrhizol, capsaicinoids, preferably capsaicin, piperine, preferably trans-piperine, glucosinolates, preferably based on non-volatile mustard oils, particularly preferably based on p-hydroxybenzyl mustard oil, methylmercapto mustard oil, methylsulfonyl mustard oil and a compound derived from these constituents.

20

25

30 17. A dosage form according to one of claims 11 to 16, characterised in that component (b) is at least one viscosity-increasing agent selected from the group consisting of microcrystalline cellulose with 11 wt.%

carboxymethylcellulose sodium (Avicel® RC 591),
carboxymethylcellulose sodium (Blanose®, CMC-Na
C300P®, Frimulsion BLC-5®, Tylose C300 P®),
polyacrylic acid (Carbopol® 980 NF, Carbopol® 981),
5 locust bean flour (Cesagum® LA-200, Cesagum® LID/150,
Cesagum® LN-1), citrus pectin (Cesapectin® HM Medium
Rapid Set), waxy maize starch (C*Gel 04201®), sodium
alginate (Frimulsion ALG (E401)®), guar flour
(Frimulsion BM®, Polygum 26/1-75®), iota carrageen
10 (Frimulsion D021®), karaya gum, gellan gum (Kelcogel
F®, Kelcogel LT100®), galactomannan (Meyprogat 150 ®),
tara bean flour (Polygum 43/1®), propylene glycol
alginate (Protanal-Ester SD-LB®), sodium hyaluronate,
apple pectin, pectin from lemon peel, sodium
15 hyaluronate, tragacanth, tara gum (Vidogum SP 200®),
fermented polysaccharide welan gum (K1A96) and xanthan
gum (Xantural 180®).

18. A dosage form according to one of claims 11 to 17,
20 characterised in that component (c) is at least one
opiate or opioid antagonist selected from the group
consisting of naloxone, naltrexone, nalmefene, nalid,
nalmexone, nalorphine, naluphine and a corresponding
physiologically acceptable compound, in particular a
25 base, salt and solvate.

19. A dosage form according to one of claims 11 to 17,
characterised in that the component (c) used is at
least one neuroleptic as a stimulant antagonist,
30 preferably selected from the group consisting of
haloperidol, promethazine, fluphenazine, perphenazine,
levomepromazine, thioridazine, perazine,
chlorpromazine, chlorprothixine, zuclopentixol,

flupentixol, prothipendyl, zotepine, benperidol,
pipamperone, melperone and bromperidol.

20. A dosage form according to one of claims 11 to 19,
5 characterised in that the component (d) emetic is
based on one or more constituents of radix ipecacuanha
(ipecac root), preferably on the constituent emetine,
and/or is apomorphine.
- 10 21. A dosage form according to one of claims 11 to 20,
characterised in that component (e) is at least one
physiologically acceptable dye.
- 15 22. A dosage form according to one of claims 11 to 21,
characterised in that component (f) is at least one
bitter substance selected from the group consisting of
aromatic oils, preferably peppermint oil, eucalyptus
oil, bitter almond oil, menthol and mixtures thereof,
fruit aroma substances, preferably from lemons,
20 oranges, limes, grapefruit and mixtures thereof,
denatonium benzoate and mixtures thereof.
- 25 23. A dosage form according to one of claims 11 to 22,
characterised in that the active ingredient or active
ingredients (A) is/are spatially separated from
component (c) and/or (d) and/or (f), wherein the
active ingredient or active ingredients (A) is/are
preferably present in at least one subunit (X) and
components (c) and/or (d) and/or (f) is/are present in
30 at least one subunit (Y), and, when the dosage form is
correctly administered, components (c) and/or (d)
and/or (f) from subunit (Y) do not exert their effect
in the body and/or on taking.

24. A dosage form according to one of claims 1 to 23,
characterised in that it contains at least one active
ingredient at least partially in controlled release
5 form.

25. A dosage form according to claim 24, characterised in
that each of the active ingredients with abuse
potential (A) is present in a controlled release
10 matrix.

26. A dosage form according to claim 25, characterised in
that component (C) and/or component (D) also serve as
a controlled release matrix material.

15 27. A process for the production of a dosage form
according to one of claims 1 to 26, characterised in
that

20 components (A), (B), (C) and the optionally present
component (D) and the optionally present components
(a) to (f) are mixed, and

25 the resultant mixture, optionally after granulation,
is press-formed to yield the dosage form with
preceding, simultaneous, or subsequent exposure to
heat.

28. A process according to claim 27, characterised in that
30 granulation is performed by means of a melt process.

29. A dosage form according to one of claims 1 to 26
obtainable by a process according to claim 27 or 28.